UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,560	03/18/2004	Tami Harel	34487	7075

67801 7590 09/03/2009

MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,560	HAREL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55,79-85,87 and 101-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55,79-85,87 and 101-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20061207, 20060919*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. PCT/IL03/00736, US 10/237,263, PCT/IL00/00566, US 09/914,889, PCT/IL00/00132, and US 60/123,532, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The Examiner was unable to find support for the combination of an electrode mounted attached to muscle tissue and electrifying that electrode in a manner suitable for blood glucose level control, as required by all pending claims. Furthermore, none of the cited applications, nor the instant application, support the scope of the currently amended claim 52, as indicated below.

Claim Objections

2. Claim 102 is objected to because of the following informalities: --is-- should be inserted after "said circuitry." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find written description support in the originally-filed application for the limitations "more than necessary for achieving a desired effect of electrification, when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient," or "sufficient to reduce blood glucose levels from a clinically elevated level to a normal level."

5. Claims 52-55, 79-85, 87, and 101-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling a blood glucose level with the signal parameters set forth on page 74 of Applicant's disclosure, does not reasonably provide enablement for any and all such parameters "suitable for blood glucose level control." The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The discussion of the experimental data on pages 74 and 75 of the disclosure provide a single set of stimulation parameters for controlling blood glucose with an electrode attached to the stomach, but the discussion on pages 44-48 indicates an extremely broad range of signal parameters suitable for said control with an electrode attached to muscle. It would require an artisan of ordinary skill to undertake undue experimentation to determine exactly which of the infinite combinations of signal parameters disclosed on pages 44-48 are effective in producing the claimed results.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 53, 82, and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In regards to claim 53, it is unclear who or what "desires" the claimed effect, or for what the electrification is "sufficient or insufficient" to do.

9. In regards to claim 82, the claim recites that the apparatus "is programmed," but no programmable element has been set forth.

10. In regards to claim 101, "said field" is lacking antecedent basis.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 52-55, 79-85, 87, and 101-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (US 5,231,988, hereinafter "Wernicke").

13. In regards to claims 52, 87, 106, 110, and 111, Wernicke discloses an apparatus for blood glucose control (abstract) comprising an implantable electrode capable of being mounted attached to muscle tissue in the abdominal cavity (col. 5, line 68 to col. 6, line 3) and circuitry that electrifies the electrode in a manner suitable for blood glucose level control (abstract). Wernicke's disclosure that the electrode is implanted "at or near the stomach" is an implicit disclosure that the electrode is "mounted attached to muscle tissue," albeit indirectly, by virtue of the innervation of the vagus into the muscle tissue at the stomach. Additionally and alternatively, Wernicke's electrode is necessarily capable of being mounted attached to stomach or duodenum muscle tissue by, *e.g.*, suturing the electrode in place on muscle tissue in the abdominal cavity, as disclosed by Applicant on pages 56 and 57 of the specification.

14. In regards to claim 53, the device is a closed-loop system (col. 7, lines 30-67) that stimulates more than necessary for achieving a desired effect of electrification (wherein the desired effect is lowering glucose by even the slightest bit - less than necessary to return glucose levels to "normal levels"), when the sensed effect does not

indicate with certainty that the electrification was sufficient or insufficient (the sensor never indicates "with certainty" because there is necessarily a certain level of imprecision and inaccuracy in real-world sensors).

15. In regards to claim 54, the circuitry is semi-open loop where a relatively long stimulation series is applied without feedback to return glucose to a normal level (col. 9, lines 41-50).

16. In regards to claim 55, the system is an open loop system (col. 9, lines 51-55).

17. In regards to claim 79, the circuitry generates an electric field that reduces glucose in a non-insulin manner (abstract; the electric field works in a "non-insulin manner" because it reduces glucose by nerve stimulation, and not by supplying insulin in any manner). Please also see below.

18. In regards to claim 81, the circuitry reduces or prevents a substantial increase in insulin secretion (abstract). Please also see below.

19. In regards to claim 82, the apparatus is programmed with information pertaining to slow-acting chemical-based insulin therapy provided to a pancreas (col. 8, lines 3-16 - knowledge that insulin is needed after meals).

20. In regards to claims 83-85, the apparatus further comprises an automatic glucose sensor to detect a need for an acute insulin response (col. 7, lines 35-40).

21. In regards to claims 103, 104, and 109, the circuitry electrifies the electrode at 5 Hz with a pulse width of less than 30ms (Table I).

22. In regards to claim 107, the electrode is electrified in synchrony with the electrical activity of the stomach (blood glucose rises with the electrical activity of the stomach associated with digestion).

23. In regards to claim 108, the apparatus reduces high blood glucose levels, but does not reduce normal blood glucose levels (col. 7, lines 30-68).

24. In regards to claims 79-81, 85, 101, 102, 105, 108, and 112, Wernicke discloses circuitry that electrifies electrodes with a frequency, pulse width, amplitude, and other signal parameters (Table I) disclosed by Applicant at pages 44-48 to be effective in producing the claimed results. As such, Wernicke's circuitry necessarily produces the claimed field, regardless of whether these properties were recognized at the time.

25. Claims 52, 55, 79-82, 85, 87, and 101-112 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchal et al. (US 7,076,306, hereinafter "Marchal").

26. In regards to claims 52, 87, 106, 110, and 111, Marchal discloses an implantable electrode configured to be mounted to a muscle tissue in the abdominal cavity (col. 5, lines 2-4) and circuitry that electrifies the electrode in a manner suitable for blood glucose control (col. 3, lines 12-20). Further, Marchal's electrode is necessarily capable of being mounted attached to a duodenum by, *e.g.*, suturing the electrode in place, as disclosed by Applicant on pages 56 and 57 of the specification becasue the material properties of the stomach and duodenum are similarly conducive to electrode attachment by, *e.g.*, suturing.

27. In regards to claim 55, the system is open-loop (Fig. 8a).

28. In regards to claim 82, the apparatus is programmed with information pertaining to slow acting chemical-based insulin therapy provided to a pancreas (col. 3, lines 21-40).

29. In regards to claims 103, 104, and 109, the device provides a frequency of 5 Hz and pulse width of 30 ms (col. 5, lines 19-45).

30. In regards to claim 107, the circuitry is electrified in synchrony with the propagation of action potentials in the stomach (col. 6, lines 11-14).

31. In regards to claims 79-81, 85, 101, 102, 105, 108, and 112, Marchal discloses circuitry that electrifies electrodes with a frequency, pulse width, amplitude, and other signal parameters (col. 5, lines 20-58) disclosed by Applicant at pages 44-48 to be effective in producing the claimed results. As such, Marchal's circuitry necessarily produces the claimed field, regardless of whether these properties were recognized at the time.

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

34. Claims 53, 54, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal in view of Wernicke. Marchal discloses the essential features of the claimed invention including closed-loop control (col. 6, lines 17-34), but does not expressly disclose circuitry configured to stimulate more than necessary for achieving a desired effect of electrification when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient, a semi-open loop system, or an automatic glucose sensor for detecting a situation requiring an acute insulin response. However, Wernicke teaches a pancreatic stimulation system comprising circuitry configured to stimulate more than necessary for achieving a desired effect of electrification when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient (col. 7, lines 30-67), a semi-open loop system (col. 9, lines 41-50), and an automatic glucose sensor for detecting a situation requiring an acute insulin response (col. 7, lines 35-40) to provide the predictable results of accurately keeping the blood glucose levels within acceptable limits.

Double Patenting

35. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

36. Claims 52-55, 79-85, 87, and 101-108 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-13, 23-30, and 66 of Application No. 10/570,576 in view of Wernicke or Marchal. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are more narrow in scope than (anticipate) the claims of the instant application, except for the broader limitation of a field that controls a level of pancreas secretion OR a blood glucose level. However, Wernicke and Marchal each individually teach that it is well known in the art to apply an electric field to the pancreas to control blood glucose levels to provide the predictable results of treating diabetes or hypoglycemia. Therefore, this modification would have been an obvious expedient.

37. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

38. Applicant's arguments with respect to claims 52-55, 79-85, 87, and 101-112 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. In regards to the previous rejection in view of Wernicke, Applicant argued that it would not be obvious to utilize muscle electrodes with Wernicke's system. However, the Examiner is not proposing any sort of modification to Wernicke's system in the rejection above, but instead that the Wernicke's nerve electrodes are capable of attachment to muscle as well because electrodes are merely pieces of conductive metal capable of being sutured to any soft tissue structure.

39. In regards to claim 53, it seems that the claimed "desired" level and "over-stimulation" level are arbitrarily chosen levels that do not necessarily correspond to thresholds or variables programmed into the claimed circuitry. In other words, it seems that anyone could arbitrarily choose the "desired" level to be less than the target level programmed into the device. Although Applicant is permitted to recite claim limitations as broadly as desired, it appears that the current language is so broad as to encompass "desired" and "over-stimulation" values that are not necessarily tied to any structure of the claimed device.

40. In regards to claim 79, although Wernicke's invention is drawn to inhibiting or promoting insulin production by the pancreas, this influence is provided by stimulation of a nerve, which is not providing insulin. The Examiner maintains that, broadly-read, this is a "non-insulin" manner.

41. In regards to claim 82, the claim language does not require any indication by a user to the system, but only an apparatus programmed with information pertaining to the claimed therapy. Eating a meal triggers the release of insulin, which the Examiner is considering in its broadest reasonable sense to be a "slow acting chemical-based insulin therapy provided to a pancreas."

42. In regards to claim 107, eating a meal initiates digestive motion of the stomach, which necessarily results in the propagation of action potentials in the stomach due to electrical activity of the stomach, as claimed.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762